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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,693	09/14/2000	Sathasivan Indiran Pather	CIMA 3.0-030 CONT II	2096
57339	7590	07/28/2006	EXAMINER	
CIMA LERNER, DAVID ET AL 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			LAMM, MARINA	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/661,693

Applicant(s)

PATHER ET AL.

Examiner

Marina Lamm

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,23,25-27,30-33,36,83,84,86,88,91,93 and 94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,23,25-27,30-33,36,83,84,86,88,91,93 and 94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/1/06; 12/27/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the amendment, Terminal Disclaimer and Declaration filed 4/25/06. Claims pending are 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94. Claims 22 and 30 have been amended.

Terminal Disclaimer

1. The terminal disclaimer filed on 4/25/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patents 6,200,604 and 6,974,590 (issued on Application SN 10/080,016) has been reviewed and is accepted. The terminal disclaimer has been recorded.

Double Patenting

2. The provisional obviousness-type double patenting rejections of Claims 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 as being unpatentable over claims 1-30 of copending Application No. **11/026,132** ('132) and claims 1-30 of copending Application No. **11/027,353** ('353) are maintained for the reasons of the record.

3. The provisional obviousness-type double patenting rejection of Claims 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 as being unpatentable over claims 1-22 of copending Application No. **11/026,327** ('327) is maintained for the reasons of the record.

4. The provisional obviousness-type double patenting rejection of Claims 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 as being unpatentable over claims 1-5,

7-10 and 12-17 of copending Application No. **10/977,029** ('029) is maintained for the reasons of the record.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. The rejection of Claims 22, 23, 26, 27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 under 35 U.S.C. 103(a) as being unpatentable over McCarty (US 5,073,374) in view of Wehling et al. (WO 91/04757) and further in view of Streisand et al. ("Buccal absorption of fentanyl is pH-dependent in dogs", Anesthesiology, (1995 Mar), 82 (3), pp. 759-64) is maintained for the reasons of the record.
7. The rejection of Claims 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 under 35 U.S.C. 103(a) as being unpatentable over Chen et al. ("Studies on formulations of fentanyl buccal adhesive tablets", Zhongguo Yiyao Gongye Zazhi, 1997, 28(3), 129-131) in view of Wehling et al. (WO 91/04757) and further in view of Streisand et al. ("Buccal absorption of fentanyl is pH-dependent in dogs", Anesthesiology, (1995 Mar), 82 (3), pp. 759-64) is maintained for the reasons of the record.

Response to Declaration and Arguments

8. The declaration under 37 CFR 1.132 filed 4/25/06 is insufficient to overcome the rejection of claims 22, 23, 25-27, 30-33, 36, 83, 84, 86, 88, 91, 93 and 94 based upon either McCarty or Chen et al. in view of Wehling et al. and further in view of Streisand

et al. as set forth in the last Office action because: the increased fentanyl permeability due to the presence of both an effervescent couple and a pH adjusting agent (i.e. base) as demonstrated in the declaration is not unexpected. More specifically, the prior art of record teaches that the buccal absorption, bioavailability and permeability of fentanyl are pH dependent and increase as the pH of the fentanyl solution becomes more basic, which is due to an increase in the fraction of unionized fentanyl. See Streisand et al. discussed previously. Also the prior art of record clearly teaches that the use of the effervescent disintegration agents in analgesic formulations provides the following benefits: masking the objectionable flavor of medicaments, facilitating the disintegration of the tablet and providing pleasant organoleptic sensation. See Wehling et al. Therefore, one skilled in the art would have expected an increased absorption, bioavailability and permeability of fentanyl through the oral mucosa following an increase in pH.

9. The Applicant argues that the teachings of McCarty cannot be combined with those of Wehling et al. "in view of the fact that Wehling requires that the active ingredient be present as coated microparticles that are to pass quickly out of the mouth and into the digestive system." See p. 9 of the reply. Contrary to the Applicant's assertion, Wehling et al. does not require that the active ingredient be present as "coated microparticles", it is merely one of the embodiments of the Wehling's invention. See Wehling et al. @ p. 6, lines 27-38.

10. Further, the Applicant argues: "There's nothing to suggest that tablet disintegration in Wehling is faster than that in McCarty or that an effervescent couple would enhance disintegration speed." See p. 10 of the reply. In response, Wehling et al. clearly teaches that "in addition to masking the objectionable flavor of medicants, the effervescence of the tablets of the present invention facilitate the disintegration thereof." See p. 6, lines 15-18. The tablets of Wehling et al. dissolve in the mouth in between about 30 seconds and about 7 minutes. See p. 13, lines 13-24.

11. Furthermore, the Applicant argues: "However, neither a true solution nor a modified drug form can be achieved in an oral cavity according Wehling since the active medicament must be covered with a protective coating to prevent exposure and the resulting coated particles are swallowed. Consequently, one skilled in the art would not look to Streisand to modify Wehling for delivery of an active medicament in the oral cavity because Wehling requires that such a condition is to be avoided." See p. 11 of the reply. In response, as discussed above, Wehling does not require the presence of a protective coating. The active ingredients of Wehling may or may not be microencapsulated.

12. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does

not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

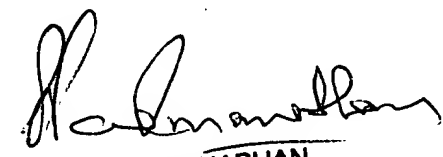
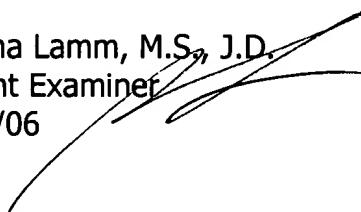
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached at (571) 272-0629.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Lamm, M.S., J.D.
Patent Examiner
7/22/06



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER